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LAMPIRAN

Lampiran 1 : PRISMA CHECKLIST 2009

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	cover
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Abstrak
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Page 4, line: 115-134
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Page 5 Line 135-167 Page 25 Line 657
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Page 25 line 647-648
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Page 25 Line 651-657-688 Page 26

			Line 664-688 Page 34 Line 862-874
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Page 34-35 Line 875-876
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Page 36 Line 892-910
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Page 27 Line 708-723
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Page 30 Line 787-794
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Page 28 Line 724-727
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Page 29 Line 758-764
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Page 31 Line 797-803
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Page 30 Line 788-794

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Page 29 Line 758-764 Page 30 Line 765-786
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	None
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Page 36 Line 892-910
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Page 35 Line 876-890
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Page 48 Line
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Page 37-41
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Page 42-47
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Page 54-55
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	None

DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	Page 56-62
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	Page 63 Line 1252-1266
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Page 64 Line 1270-1297
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Page 65 Line 1310-1311

Page 1 of 2

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org




Lampiran 2: Critical Appraisal Skill Programme RCT Checklist



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CASP Checklist: 11 questions to help you make sense of a **Randomised Controlled Trial**

How to use this appraisal tool: Three broad issues need to be considered when appraising a trial:

-  Are the results of the study valid? (Section A)
-  What are the results? (Section B)
-  Will the results help locally? (Section C)

The 11 questions on the following pages are designed to help you think about these issues systematically. The first three questions are screening questions and can be answered quickly. If the answer to both is "yes", it is worth proceeding with the remaining questions. There is some degree of overlap between the questions, you are asked to record a "yes", "no" or "can't tell" to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

About: These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised controlled trial & systematic review) were based on JAMA 'Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL, and Cook DJ), and piloted with health care practitioners.

For each new checklist, a group of experts were assembled to develop and pilot the checklist and the workshop format with which it would be used. Over the years overall adjustments have been made to the format, but a recent survey of checklist users reiterated that the basic format continues to be useful and appropriate.

Referencing: we recommend using the Harvard style citation, i.e.: *Critical Appraisal Skills Programme (2018). CASP (insert name of checklist i.e. Randomised Controlled Trial) Checklist. [online] Available at: URL. Accessed: Date Accessed.*

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Paper for appraisal and reference:.....

Section A: Are the results of the trial valid?

1. Did the trial address a clearly focused issue?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: An issue can be 'focused' in terms of

- the population studied
- the intervention given
- the comparator given
- the outcomes considered

Comments:

2. Was the assignment of patients to treatments randomised?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- how this was carried out
- was the allocation sequence concealed from researchers and patients

Comments:

3. Were all of the patients who entered the trial properly accounted for at its conclusion?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- was the trial stopped early
- were patients analysed in the groups to which they were randomised

Comments:

Is it worth continuing?

4. Were patients, health workers and study personnel 'blind' to treatment?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments:

5. Were the groups similar at the start of the trial

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider
• other factors that might affect the outcome, such as; age, sex, social class

Comments:

6. Aside from the experimental intervention, were the groups treated equally?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments:

Section B: What are the results?

7. How large was the treatment effect?

HINT: Consider

- what outcomes were measured
- Is the primary outcome clearly specified
- what results were found for each outcome

Comments:

8. How precise was the estimate of the treatment effect?

HINT: Consider

- what are the confidence limits

Comments:

Section C: Will the results help locally?

9. Can the results be applied to the local population, or in your context?

Yes

Can't Tell

No

HINT: Consider whether

- the patients covered by the trial are similar enough to the patients to whom you will apply this
- how they differ

Comments:

10. Were all clinically important outcomes considered?

Yes

Can't Tell

No

HINT: Consider whether

- there is other information you would like to have seen
- if not, does this affect the decision

Comments:

11. Are the benefits worth the harms and costs?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider
• even if this is not addressed by the trial, what do **you** think?

Comments:

Lampiran 3: Critical Appraisal Skill Programme Cohort Study Checklist



CASP Checklist: 12 questions to help you make sense of a **Cohort Study**

How to use this appraisal tool: Three broad issues need to be considered when appraising a cohort study:

- ▶ Are the results of the study valid? (Section A)
- ▶ What are the results? (Section B)
- ▶ Will the results help locally? (Section C)

The 12 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is "yes", it is worth proceeding with the remaining questions. There is some degree of overlap between the questions, you are asked to record a "yes", "no" or "can't tell" to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

About: These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised controlled trial & systematic review) were based on JAMA 'Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL, and Cook DJ), and piloted with health care practitioners.

For each new checklist, a group of experts were assembled to develop and pilot the checklist and the workshop format with which it would be used. Over the years overall adjustments have been made to the format, but a recent survey of checklist users reiterated that the basic format continues to be useful and appropriate.

Referencing: we recommend using the Harvard style citation, i.e.: *Critical Appraisal Skills Programme (2018). CASP (insert name of checklist i.e. Cohort Study) Checklist. [online] Available at: URL. Accessed: Date Accessed.*

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Paper for appraisal and reference:.....

Section A: Are the results of the study valid?

1. Did the study address a clearly focused issue?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: A question can be 'focused' in terms of

- the population studied
- the risk factors studied
- is it clear whether the study tried to detect a beneficial or harmful effect
- the outcomes considered

Comments:

2. Was the cohort recruited in an acceptable way?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Look for selection bias which might compromise the generalisability of the findings:

- was the cohort representative of a defined population
- was there something special about the cohort
- was everybody included who should have been

Comments:

Is it worth continuing?

3. Was the exposure accurately measured to minimise bias?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: Look for measurement or classification bias:
- did they use subjective or objective measurements
 - do the measurements truly reflect what you want them to (have they been validated)
 - were all the subjects classified into exposure groups using the same procedure

Comments:

4. Was the outcome accurately measured to minimise bias?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: Look for measurement or classification bias:
- did they use subjective or objective measurements
 - do the measurements truly reflect what you want them to (have they been validated)
 - has a reliable system been established for detecting all the cases (for measuring disease occurrence)
 - were the measurement methods similar in the different groups
 - were the subjects and/or the outcome assessor blinded to exposure (does this matter)

Comments:

5. (a) Have the authors identified all important confounding factors?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT:

- list the ones you think might be important, and ones the author missed

Comments:

5. (b) Have they taken account of the confounding factors in the design and/or analysis?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT:

- look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors

Comments:

6. (a) Was the follow up of subjects complete enough?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- the good or bad effects should have had long enough to reveal themselves
- the persons that are lost to follow-up may have different outcomes than those available for assessment
- in an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort

6. (b) Was the follow up of subjects long enough?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments:

Section B: What are the results?

7. What are the results of this study?

HINT: Consider

- what are the bottom line results
- have they reported the rate or the proportion between the exposed/unexposed, the ratio/rate difference
- how strong is the association between exposure and outcome (RR)
- what is the absolute risk reduction (ARR)

Comments:

8. How precise are the results?

HINT:

- look for the range of the confidence intervals, if given

Comments:

9. Do you believe the results?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: Consider
- big effect is hard to ignore
 - can it be due to bias, chance or confounding
 - are the design and methods of this study sufficiently flawed to make the results unreliable
 - Bradford Hills criteria (e.g. time sequence, dose-response gradient, biological plausibility, consistency)

Comments:

Section C: Will the results help locally?

10. Can the results be applied to the local population?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: Consider whether
- a cohort study was the appropriate method to answer this question
 - the subjects covered in this study could be sufficiently different from your population to cause concern
 - your local setting is likely to differ much from that of the study
 - you can quantify the local benefits and harms

Comments:

11. Do the results of this study fit with other available evidence?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments:

12. What are the implications of this study for practice?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- one observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making
 - for certain questions, observational studies provide the only evidence
 - recommendations from observational studies are always stronger when supported by other evidence

Comments:

Lampiran 4: The Cochrane collaborations tool for assessing risk of bias

Cochrane Collaboration's tool for assessing risk of bias (adapted from Higgins and Altman13)

Bias domain	Source of bias	Support for judgment	Review authors' judgment (assess as low, unclear or high risk of bias)
Selection bias	Random sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence
	Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrolment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment
Performance bias	Blinding of participants and personnel*	Describe all measures used, if any, to blind trial participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study
Detection bias	Blinding of outcome assessment*	Describe all measures used, if any, to blind outcome assessment from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	Detection bias due to knowledge of the allocated interventions by outcome assessment
Attrition bias	Incomplete outcome data*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition or exclusions where reported, and any reinclusions in analyses for the review	Attrition bias due to amount, nature, or handling of incomplete outcome data
Reporting bias	Selective reporting	State how selective outcome reporting was examined and what was found	Reporting bias due to selective outcome reporting
Other bias	Anything else, ideally Prespecified	State any important concerns about bias not covered in the other domains in the tool	Bias due to problems not covered elsewhere

Assessments should be made for each main outcome or class of outcomes □

Lampiran 5: Level of evidence

5/7/2020

Oxford Centre for Evidence-based Medicine - Levels of Evidence (March 2009) - CEBM

Search

Oxford Centre for Evidence-based Medicine – Levels of Evidence (March 2009)

What are we to do when the irresistible force of the need to offer clinical advice meets with the immovable object of flawed evidence? All we can do is our best: give the advice, but alert the advisees to the flaws in the evidence on which it is based.

The CEBM 'Levels of Evidence 1' document sets out one approach to systematising this process for different question types.

(For definitions of terms used see our [glossary](https://www.cebm.net/glossary/) (<https://www.cebm.net/glossary/>))

Level	Therapy / Prevention, Aetiology / Harm	Prognosis	Diagnosis	Differential diagnosis / symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR* validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR* with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval ⁱ)	Individual inception cohort study with > 80% follow-up; CDR* validated in a single population	Validating** cohort study with good*** reference standards; or CDR* tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none [§]	All or none case-series	Absolute SpPins and SnNouts***	All or none case-series	Absolute better-value or worse-value analyses****
2a	SR (with homogeneity*)	SR (with homogeneity*)	SR (with homogeneity*)	SR (with homogeneity*)	SR (with homogeneity*)

<https://www.cebm.net/2009/06/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/>

1/4

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		cohort studies or untreated control groups in RCTs	studies		studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR* or validated on split-sample§§§ only	Exploratory** cohort study with good* * * reference standards; CDR* after derivation, or validated only on split-sample§§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-	Case-series (and poor quality prognostic	Case-control study, poor or non-independent	Case-series or superseded reference standards	Analysis with no sensitivity analysis

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5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"
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Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1996. Updated by Jeremy Howick March 2009.

Notes

Users can add a minus-sign "-" to denote the level of that fails to provide a conclusive answer because:

- EITHER a single result with a wide Confidence Interval
- OR a Systematic Review with troublesome heterogeneity.

Such evidence is inconclusive, and therefore can only generate Grade D recommendations.

*	By homogeneity we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "-" at the end of their designated level.
*	Clinical Decision Rule. (These are algorithms or scoring systems that lead to a prognostic estimation or a diagnostic category.)
* _i	See note above for advice on how to understand, rate and use trials or other studies with wide confidence intervals.
§	Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.
§§	By poor quality cohort study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the

Search

§§§	Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples.
**	An "Absolute SpPin" is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis. An "Absolute SnNout" is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis.
††	Good, better, bad and worse refer to the comparisons between treatments in terms of their clinical risks and benefits.
***	Good reference standards are independent of the test, and applied blindly or objectively to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a non-independent reference standard (where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference') implies a level 4 study.
****	Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equally or more expensive.
**	Validating studies test the quality of a specific diagnostic test, based on prior evidence. An exploratory study collects information and trawls the data (e.g. using a regression analysis) to find which factors are 'significant'.
***	By poor quality prognostic cohort study we mean one in which sampling was biased in favour of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors.
****	Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (for example 1-6 months acute, 1 – 5 years chronic)

Grades of Recommendation

A	consistent level 1 studies
B	consistent level 2 or 3 studies or extrapolations from level 1 studies
C	level 4 studies or extrapolations from level 2 or 3 studies
D	level 5 evidence or troublingly inconsistent or inconclusive studies of any level

"Extrapolations" are where data is used in a situation that has potentially clinically important differences than the original study situation.

Lampiran 6: Rekomendasi Persetujuan Etik

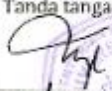

	KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN KOMITE ETIK PENELITIAN KESEHATAN RSPTN UNIVERSITAS HASANUDDIN RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR Sekretariat : Lantai 2 Gedung Laboratorium Terpadu JL. PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10 MAKASSAR 90045. Contact Person: dr. Agussalim Bukhari, M.Med,PhD, Sp.GK TELP. 08124183058, 0411 5280303, Fax : 0411-581431	
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REKOMENDASI PERSETUJUAN ETIK

Nomor : 670/UN4.6.4.5.31/ PP36/ 2020

Tanggal: 21 Oktober 2020

Dengan ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol berikut ini telah mendapatkan Persetujuan Etik :

No Protokol	UH20100585	No Sponsor	
Peneliti Utama	Etty,S.Kep,Ns	Sponsor	
Judul Peneliti	Efektivitas Penggunaan Madu Topikal Terhadap Penyembuhan Pressure Ulcer: A Systematic Review		
No Versi Protokol	1	Tanggal Versi	19 Oktober 2020
No Versi PSP		Tanggal Versi	
Tempat Penelitian	Fakultas Keperawatan Universitas Hasanuddin Makassar		
Jenis Review	<input checked="" type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 21 Oktober 2020 sampai 21 Oktober 2021	Frekuensi review lanjutan
Ketua Komisi Etik Penelitian Kesehatan FKUH	Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)	Tanda tangan 	
Sekretaris Komisi Etik Penelitian Kesehatan FKUH	Nama dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (K)	Tanda tangan 	

Kewajiban Peneliti Utama:

- Menyampaikan Amendemen Protokol untuk persetujuan sebelum di implementasikan
- Menyerahkan Laporan SAE ke Komisi Etik dalam 24 jam dan dienkapsi dalam 7 hari dan Laporan SUSAR dalam 72 jam setelah Peneliti Utama menerima laporan
- Menyerahkan Laporan Kemajuan (progress report) setiap 6 bulan untuk penelitian resiko tinggi dan setiap setahun untuk penelitian resiko rendah
- Menyerahkan laporan akhir setelah Penelitian berakhir
- Melaporkan penyimpangan dari protokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan